



The Ryan White CARE Act was enacted in 1990 to provide primary care and support services to low-income and uninsured individuals living with HIV/AIDS. The CARE Act is administered by the Health Resources and Services Administration and its HIV/AIDS Bureau.

AIDS DRUG ASSISTANCE PROGRAMS (ADAPs) SECTION 340B DRUG DISCOUNT PROGRAM

In recent years, AIDS Drug Assistance Programs (ADAPs) have witnessed unprecedented growth in program enrollment, utilization, and expenditures. These increases began with the Food and Drug Administration's (FDA) approval of protease inhibitors (PIs). When used in combination with other antiretrovirals, PIs have proven to be very effective in prolonging life and improving the quality of life for people with HIV/AIDS.

The high cost of combination therapy—\$10,000 to \$15,000 annually—has placed pressure on ADAPs to adopt a wide variety of cost-containment strategies to maximize resources. Participation in the Section 340B Drug Discount Program is the most frequently used and most effective of these cost-saving strategies available to ADAPs. The purpose of the Section 340B Program is to lower the cost of acquiring outpatient drugs so that covered entities can serve more patients and improve service quality.

Veterans' Health Care Act of 1992

Public Law 102-585, the Veterans' Health Care Act of 1992, was designed to establish price controls to limit the cost of drugs to Federal purchasers and to certain grantees of Federal agencies. There are several sections to the Act. Section 601 amends the Medicaid rebate program; Section 602 provides drug discounts to certain grantees and eligible entities; and Section 603 covers what is often referred to as "Department of Defense" pricing and the Federal Supply Schedule—both programs are administered by the Department of Veterans Affairs.

Section 340B

Section 602 of the Act enacted Section 340B of the Public Health Services Act, which is administered by the Office of Pharmacy Affairs (OPA), [formerly known as the Office of Drug Pricing (ODP)]. Section 340B provides that as a condition for participation in Medicaid, drug manufacturers who sell covered drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of the Department of Health and Human Services. In this agreement, the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the statutory ceiling price. The ceiling price is the average manufacturers' price (AMP) reduced by the Medicaid rebate percentage. The discount will vary according to the drug purchased. Section 340B identifies those entities that are eligible for 340B pricing and specific requirements for participation in the program. All CARE Act grantees, including ADAPs, are covered entities. ADAPs have two methods of accessing the Section 340B Drug Discount Program: through a point of purchase system or the ADAP 340B rebate option. (The latter option is available only to ADAPs.)

What is ADAP?

AIDS Drug Assistance Programs (ADAPs) are authorized under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. CARE Act-funded programs, including ADAP, are the largest source of Federal funding specifically directed to provide primary care, treatment, and support services for low-income persons living with HIV disease. States are required to use a portion of their funds to provide medications to treat HIV disease, including measures for the prevention and treatment of opportunistic disease.

For FY 2001, States project that approximately 137,800 individuals with HIV disease who have limited or no coverage from private insurance or Medicaid will access ADAPs. In any given month, ADAPs anticipate serving almost 79,000 people.

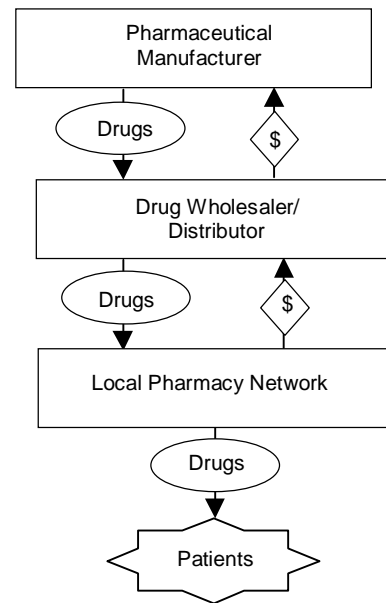
Point of Purchase System

Currently, 22 ADAPs participate in the point of purchase system. OPA Federal guidelines require that these ADAPs purchase drugs directly from manufacturers, wholesalers, or through a purchasing agent and that they dispense the drugs either through their own pharmacy or through a single contract service provider. In all cases, the participating entity must take ownership of the drugs.

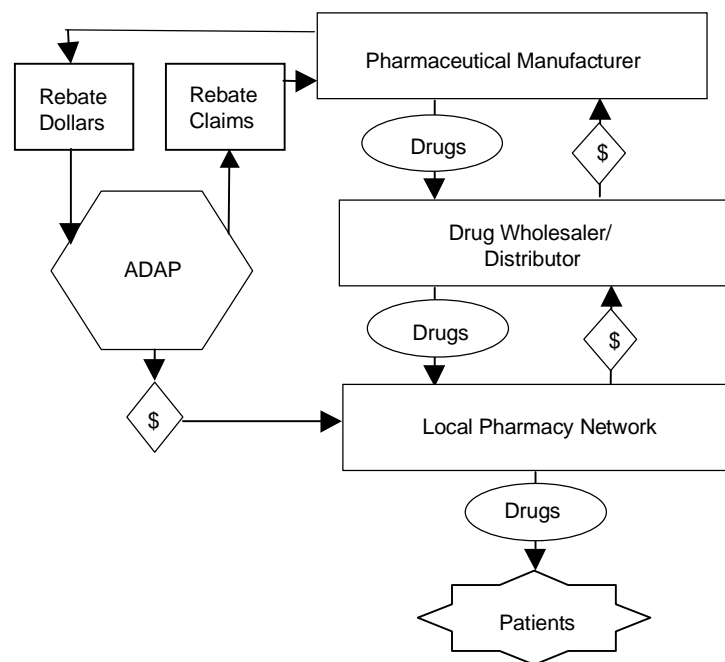
ADAP Rebate Option

On June 29, 1998, a *Federal Register* notice was published recognizing a rebate option for ADAPs as an alternative method to access the Section 340B Drug Discount Program. Currently, 26 ADAPs have transitioned from voluntary manufacturer rebate agreements to the ADAP 340B rebate option. The rebate option is designed to allow ADAPs currently using a reimbursement model to achieve cost savings that are closer to the savings received through the point of purchase system. ADAPs using the rebate option have the ability to obtain rebates on all covered outpatient drugs on the ADAP formulary. In cooperation with the Health Resources and Services Administration (HRSA) and State ADAP representatives, the National Alliance of State and Territorial AIDS Directors (NASTAD) developed uniform Conditions of Participation that ADAPs may use to standardize the process of submitting and receiving rebate claims from manufacturers.

How the Point of Purchase System Works



How the ADAP 340B Rebate Option Works



Technical Assistance

ADAPs seeking further information about the Section 340B Drug Discount Program, or that would like technical assistance in transitioning to either the point of purchase system or the ADAP rebate option, should contact their Title II project officer.